JUL - 2 2001

510(k) Summary K011199

1. SUBMISSION STATEMENT

Trade Name:	Bausch & Lomb Proview™ Eye Pressure Monitor
Common Name:	Tonometer
Classification:	Tonometer and Accessories - 21 CFR 886 1930
Class:	Class II
Product Code:	86 HKY
Manufacturer:	Bausch & Lomb Incorporated 1400 North Goodman Street Rochester, NY 14603-0450
Contact Person:	Douglas J. Fortunato
Telephone:	(716) 338-5477
Fax:	(716) 338-0702
Email address:	dfortunato@bausch.com
Establishment Registration Number	1313525

3. PREMARKET NOTIFICATION NUMBER

4. INDICATIONS FOR USE

The Bausch & Lomb Proview™ Eye Pressure Monitor is intended for use in clinical and home test use for measuring intraocular pressure. It is intended as a monitoring device for intraocular pressure.

5. DESCRIPTION OF THE DEVICE

The Bausch & Lomb Proview™ Eye Pressure Monitor is a hand held pressure measuring device that consists of three molded plastic components and an internal stainless steel metal spring. The probe is spring loaded within the fiduciary of the instrument.

The device itself appears similar to a pen. There is a measuring scale on the outside of the tube-like structure that records the visible readings. Closer to the probe are finger grips. The distal end of the device is a reset button that resets the probe for subsequent readings. The probe is housed within the tube-like structure. At the distal end of the probe is a metal spring, which provides resistance at pressures applied by the probe for reading the intraocular pressure. Once the pressure is taken, the probe must be reset by release of the reset button.

The probe is a soft blunt ended component that is to place upon the individuals closed upper lid near the nasal portion of the eyelid.

The components of the device are medical grade stainless steel spring housed at the distal end of the probe. The probe and the outer housing are comprised of molded Noryl Plastic.

6. **STATEMENT OF EQUIVALENCE**

There is only one difference between the Bausch & Lomb Proview™ Eye Pressure Monitor and the predicate device, which is the FPT/Fresco Phosphene Tonometer, as cleared under 510(k) Premarket Notification No. K991840 dated March 20, 2000. The probe and the outer housing of the Bausch & Lomb Proview™ Eye Pressure Monitor are comprised of molded Noryl Plastic, where as the probe and the outer housing of the FPT/Fresco Phosphene Tonometer are made of molded ABS Plastic.

7. **DESCRIPTION OF EQUIVALENCE**

The Bausch & Lomb Proview™ Eye Pressure Monitor is identical in every aspect to the predicate device, which is the FPT/Fresco Phosphene Tonometer, as cleared under 510(k) Premarket Notification No. K991840 dated March 20, 2000.

8. **SAFETY AND EFFICACY INFORMATION**

The safety and efficacy of the FPT/Fresco Phosphene Tonometer was demonstrated in 510(k) Premarket Notification No. K991840 cleared on March 20, 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2001

Mr. Douglas J. Fortunato
Director, Regulatory Affairs
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14603-0450

Re: K011199
Trade Name: Proview™ Eye Pressure Monitor
Regulation Number: 21 CFR 886.1930
Regulatory Class: Class II
Product Code: 86 HKY
Dated: May 25, 1999
Received: May 28, 1999

Dear Mr. Fortunato:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Rochester, NY 14603-0450

Indication for Use Statement

510(k) Number (if known): K011199

Device Name: Bausch & Lomb Proview™ Eye Pressure Monitor

Indications for Use:

The Bausch & Lomb Proview™ Eye Pressure Monitor is intended for use in clinical and home test use for measuring intraocular pressure. It is intended as a monitoring device for intraocular pressure.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011199

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